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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

(Docket No. 99N-4783)

Re: **Proposed Rule on Good Guidance Practices, 65 Fed. Reg. 7321 (Feb. 14, 2000)**

Dear Dockets Management:

Pfizer Inc. submits these comments on the proposed rule: "Administrative Practices and Procedures; Good Guidance Practices," published in the Federal Register on February 14, 2000.

1. Introduction

The proposed rule is intended to implement section 701(h) of the Federal Food, Drug, and Cosmetic Act ("the Act"), which was enacted by section 405 of the Food and Drug Administration Modernization Act of 1997. Section 701(h) directs FDA to "develop guidance documents with public participation," and sets procedural requirements respecting the issuance and use of guidance documents. Section 701(h) also requires FDA, by July 1, 2000, to "promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents."

2. Comments on the Proposed Rule

Pfizer offers the following comments and recommendations regarding the proposed rule.

(a) Proposed § 10.115(i) (standard elements)

In addition to the other elements identified in the proposed rule, Pfizer suggests that each guidance document (and draft guidance) include a statement identifying its "Level." Moreover, if the guidance is a "Level 1" guidance, and has been issued without prior public participation, the guidance should set forth the reasons for FDA's determination that prior public participation was "not feasible or appropriate." This information will assist regulated industry by indicating whether public input was sought before a guidance's issuance; whether FDA intends the guidance as a means for communicating new or different regulatory policies or interpretations; and whether FDA believes there to be an urgency or other circumstance justifying implementation of the guidance without prior public participation.

(b) Proposed § 10.115(h)(4) (list of proposed guidances)

FDA's current practice is to publish a list of proposed guidances semi-annually. The proposed rule, however, provides for annual publication. Pfizer recommends that FDA continue the semi-annual schedule, prioritize the list to indicate when a guidance is likely to be issued or revised, and include in the list the status of each item (e.g. whether a guidance has issued in draft or final, perhaps with a link to the document).

Pfizer finds the list of proposed guidances helpful in indicating what areas FDA is focusing on, and whether regulatory clarification can be expected. The absence of up-to-date information on when FDA intends to address an item, however, diminishes the list's value. By providing approximate time-frames for Agency action respecting each item on the list, FDA could not only help regulated companies better direct their resources towards issues as they arise, but also perhaps better coordinate the Agency's own efforts.

(c) Proposed § 10.115(g)(2) (exception to prior public participation)

As proposed, this provision states: "FDA will not seek your comment before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate." Although this language parallels the statute, the preamble to the proposed rule suggests that FDA may apply this provision more broadly than Congress intended.

In the preamble, FDA indicates that it will implement Level 1 guidance documents without prior public participation in the following circumstances:

> (1) There are public health reasons for immediate implementation of the guidance document; (2) there is a statutory requirement, executive order, or court order that requires immediate implementation; or (3) the guidance document presents a less burdensome policy that is consistent with public health.

65 Fed. Reg. at 7324. FDA also "reserves the authority to provide for other exceptions that are consistent with section 701(h)(1)(C) of the act, if the need arises." *Id.*

FDA should make clear in the proposed rule that, consistently with Congressional intent, the Agency may waive the requirement of prior public participation position "only in rare and extraordinary circumstances where there is a compelling rationale," including "reasons such as public health." H. Rep. 105-310, at 74 (1997). The current preamble language stating that FDA will follow the statute is uninformative and lacks the substance that industry reasonably expects to find in rulemakings.

Sincerely,

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